REMARKS

I. Status Of The Claims.

Claims 1-24, and 27 are pending in the application. Claims 1, 4-9, 10-13, 17-18, 22-24, and 26 are rejected under 35 U.S.C. § 102(e), and Claims 2-3, 14-16, and 19-21 are rejected under 35 U.S.C. § 103(a). This Response amends Claims 1, 12, 18, 22- 23, and 27. These amendments clarify limitations that are inherent in the previously presented claims. As such, these amendments (a) place the claims in better form for appeal should the Office maintain the current rejection; (b) do not add new matter; (c) do not present new issues requiring further consideration or search; and (d) do not present any additional claims. According to United States Patent Office practice and procedure, entry of these amendments is proper. Applicants request entry of these amendments, reconsideration, and allowance of all claims.

II. Amendments to the Claims.

Claims 1, 22, and 27.

Elements a) and b) in Claim 1 has been amended to clarify that the first detecting light beam has "a first wavelength", and that the second detecting light beam has "a wavelength different than the first detecting light beam". Claims 22 and 27 are similarly amended. This feature of the invention is described on pages 4 and 5 of the specification. The phrase "a wavelength different than the first detecting light beam" is an inherent limitation in the claim as originally filed, which is now expressly stated to clarify Applicants claimed invention. A wavelength of light that is substantially blocked by serum, plasma, and cells, but is transmitted by the material is inherently different than the wavelength of light in the first detecting light beam, which is transmitted by serum, plasma, and the material but substantially blocked by cells.

Element e) in Claims 1, 22, and 27 has been amended to clarify that the detected portions are the "detected portions of the first and second detecting light beams." The phrase "of the first and second detecting light beams" is an inherent limitation in the claim as originally filed, which is now expressly stated to clarify Applicants claimed invention.

The amended claims now expressly state that which was already inherent in the claims as originally filed and the addition of the above-described amendments does not change the scope of the claims or add new matter. Should the Office maintain the current basis for rejection of the claims, this amendment will place the application in better form for appeal. Entry of the amendments to Claims 1, 22, and 27 is respectfully requested.

Claims 12 and 18.

Minor amendments have been made to elements a) and b) of Claims 12 and 18 so these claims now have a format that is consistent with the remainder of the claims.

Element e) in Claims 12 and 18 has been amended to clarify that the detected portions are the "detected portions of the first and second detecting light beams." The phrase "of the first and second detecting light beams" is an inherent limitation in the claim as originally filed, which is now expressly stated to clarify Applicants claimed invention.

The amended claims now expressly state that which was already inherent in the claims as originally filed and the addition of the above described amendments does not change the scope of the claims or add new matter. Should the Office maintain the current basis for rejection of the claims, this amendment will place the application in better form for appeal. Entry of the amendments to Claims 12 and 18 is respectfully requested.

Claim 23.

Element a) of Claim 23 has been amended to clarify that the light beam is "a detecting light beam of infrared light being ~~that is~~ substantially blocked by serum or plasma and the cells but substantially transmitted by the material and the gel, a portion of the detecting light beam being transmitted through the container; . . ." The term "plasma" is added to claim 7 for clarity, as "serum or plasma" is recited in the preamble of the claim. The phrase "of infrared light being" is added to clarify Applicants claimed invention. As described on pages 4-5 of the specification, a wavelength of light that is blocked by serum or plasma and cells, but transmitted by the material, is in the long wavelength of light, such as the infrared range.

Element e) in Claim 23 has been amended to clarify that the detected portions are the "detected portions of the detecting light beam." The phrase "of the detecting light beam" is an inherent limitation, which is now expressly stated to clarify Applicants claimed invention.

The amendments to Claim 23 do not add new matter. Should the Office maintain the current basis for rejection of the claims, this amendment will place the application in better form for appeal. Entry of the amendment to Claim 23 is respectfully requested.

III. Applicants Invention.

Applicants' invention is a sample level detection system and methods where the spectral properties of a sample container, serum, plasma, red blood cells, and gel can be used to identify interfaces in a sample container.

In one embodiment of Applicants' invention, multiple light sources having different wavelengths are used to identify interfaces in a sample container. As described on page 4, lines 19-30, even in the absence of gel to separate the different blood components, the combination of two different wavelengths of light can be used to detect the interfaces in a sample tube. As described on page 3 of the specification, Applicants recognized that serum, plasma, and cells are substantially opaque to light at long wavelengths. Applicants further recognized that by combining the spectral measurements of light having a long wavelength with the spectral measurements of light having a shorter wavelength, where serum is absorbed, that the interfaces of the different components in a blood sample could be determined, even in the absence of gel.

According to one embodiment of Applicants' invention, a first light source, which is substantially blocked by cells, but transmitted by serum and plasma is projected onto a container. A second light source, which is blocked by serum, plasma, and cells, is also projected onto the container. The portion of the unblocked light sources that is transmitted through the container from each light source is then detected. The detected light readings of each transmitted light source are then used to determine the interfaces in a container. The interfaces, different light sources, and light readings of this embodiment of the invention are illustrated in Figure 3.

In another embodiment of Applicants' invention, when gel is present in a sample, a single light source that is transmitted by the container material and gel, but that is not transmitted by serum or plasma and gel, can be used to identify interfaces in a sample container. As described on page 4, lines 10-18, an infrared light source can be used to "see

through" different sections of a sample, and the infrared light can be used to detect the interfaces in a sample tube. According to this embodiment of Applicants' invention, an infrared light source, which is blocked by serum or plasma, and cells, but that is transmitted by the container material and gel is projected onto a container. The portion of the unblocked light source that is transmitted through the container and the gel is then detected and the detected light readings are then used to determine the interfaces in the container. This embodiment of the invention is illustrated in Figure 2.

Applicants' invention allows for automated determination of sample interfaces that traditionally were visually detected. An additional advantage of the invention is that the interfaces can be determined where there are multiple labels on the sample container. Accordingly, Applicants' invention provides an inexpensive and reliable method for determining sample volume and interfaces for conducting required sample tests in the presence or absence of gel in a sample, and in the presence or absence of labels on a sample container.

IV. The 35 U.S.C. § 102(e) Rejection.

Claims 1, 4-8, 10-13, 17-18, 22-24, and 27 are rejected under 35 U.S.C. § 102(e), as anticipated by Cadell et al. (US 6,195,158 B1) for the reasons stated in numbered paragraph 2 of the Office Action dated 11/20/2003 (the "Office Action"). Claims 1, 9, and 27 are rejected under 35 U.S.C. § 102(e), as anticipated by Kawano (US 2002/0067476) for the reasons stated in numbered paragraph 3 of the Office Action. Neither Cadell et al. nor Kawano describe all of the limitations of the claimed invention. Applicants request consideration the following comments and allowance of all pending claims.

A. Cadell et al. and Kawano Do Not Describe A Light Beam That Is Substantially Blocked By Serum or Plasma But Is Substantially Transmitted by A Container Material.

Claim 1 is limited to a "detecting light beam being substantially blocked by serum, plasma, and cells, but substantially transmitted by the material . . . ." Claims 12, 18, 22-23 and 27 are similarly limited. Neither Cadell et al., nor Kawano describe this limitation. Applicants request reconsideration and allowance of all claims, Claims 1, 12, 18, 22-23, and 27, and their dependent claims, on this basis.

1. Cadell et al. Docs Not Describe A Light Beam That Is Substantially Blocked By Serum or Plasma.

Cadell et al. describes a device and methods for (a) reading a bar code on a specimen; (b) determining the gel level of a specimen and the height of fluid above the gel; and (c) a spectrophotometric device to irradiate and measure radiation from the specimen to determine if the specimen contains interferents. In the preferred embodiments, a linear array of LEDs or alternatively, a diode laser provides the radiation source to determine liquid height and gel level. (Col. 4, lines 1-46). In this determination, the transmitted light is used to determine liquid height and gel level. Further described is an apparatus and method where the radiation from the spectrophotometer, or other appropriate source is transmitted through the label, container and specimen. (Col. 2, lines 24-65). In this step, a spectrophotometer is used to determine interferents in a sample by measurement of absorption of light in serum or plasma with a radiation source. (Abstract; Col. 4, lines 47-63).

Nowhere in Cadell et al. is the feature of Applicants' invention, a light beam that is substantially ***blocked*** by serum or plasma, but that is transmitted by the material, described. This feature of Applicants invention is graphically represented in Figure 6 (i.e., the lower graph). Figure 6 shows the magnitude of transmittance of infrared light vs. tube position. By focusing a specific wavelength of light incrementally over the length of the tube, and measuring transmitted light, or the absence of transmitted light, interfaces are determined, e.g., container height (material/air interface); sample level (material/serum interface); gel level (serum/gel interface); and cell level (gel/cell interface). In constrast to Applicants' invention, Cadell et al. describes using light that is transmitted or absorbed through the material, the serum, or plasma and gel to determine sample height or interferents. This is fundamentally different than Applicants invention. Applicants recognized that certain long wavelengths of light are ***not*** transmitted by serum, plasma, and cells, but are transmitted by the material and used these spectral properties to determine sample interfaces. This is not described in Cadell et al.

Cadell et al. does not disclose a light beam that is substantially blocked by serum or plasma. The Applicants strongly disagree with the assertion of the Office on page 2,

paragraph 2(b) through page 3, line 2 that Cadell et al. discloses this feature of Applicants invention. Accordingly, Applicants request withdrawal of the rejection under 35 U.S.C. § 102(e) of Claims 1, 4-8, 10-13, 17-18, 22-24, and 27 over Cadell et al.

2. Kawano Does Not Describe A Light Beam That Is Substantially Blocked By Serum or Plasma.

Kawano describes describes using light in the 700-1100 nm range to ***analyze*** the object characteristics of the blood. The analysis is performed by measuring the near infrared absorption spectrum of a sample in which absorption is plotted against wavelength. (See, e.g., paragraphs [0036]-[0041]). By necessity, to analyze the absorption components of blood, light must be transmitted through the sample and not substantially blocked by the blood sample (i.e., serum or plasma) as claimed by Applicants. The contrast between Applicants claimed invention and Kawano is illustrated by comparing Applicants' Figure 6, showing substantially no transmittance by serum, and Figures 4 and 5 of Kawano that show the magnitude of Absorbance vs. wavelength of blood samples (i.e., the NIR light is transmitted and ***not*** substantially blocked by the blood samples in Kawano).

Kawano does not describe a light beam that is substantially blocked by serum or plasma. Applicants strongly disagree with the assertion of the Office on page 5, par. 3(b) that paragraph 33, line 6 through paragraph 34, line 5 of Kawano discloses this feature. Accordingly, Applicants request withdrawal of the rejection under 35 U.S.C. § 102(e) of Claims 1, 9, and 27 over Kawano.

B. Cadell et al. and Kawano Do Not Describe Determining The Location Of An Interface From Multiple Detected Light Beams Of A Different Wavelength.

Claim 1 is limited to Claim 1 is limited to "a first detecting light beam having a first wavelength. . . ; a second detecting light beam having a second wavelength different than the first wavelength . . . ; and determining the location of at least one interface from the detected portions of the first and second detecting light beams." Independent claims, Claims 12, 18, 22, and 27 are each similarly limited. As detailed below, neither Cadell et al. nor Kawano describe this limitation. Accordingly, reconsideration and allowance of Independent Claims 1, 12, 18, 22, and 27 and their dependent claims is respectfully requested.

1. Cadell et al. Does Not Describe Determining The Location Of An Interface From Multiple Detected Light Beams Of A Different Wavelength.

Cadell et al. describes describes using LEDs 16 to calculate fluid volume from the measured tube diameter and the measured height of fluid above the gel barrier. (*See, e.g.*, Cadell et al. col. 2, lines 24- 65; col. 3, line 66 through col. 4, line 31). Alternately, Cadell et al. discloses measuring gel level and height of fluid with a diode laser 28. Cadell et al. also determines sample type and temperature, and measures interferents with a spectrophotometer. Contrary to the assertion of the Office on pages 2-3 of the Office Action, this disclosure does not constitute determining the location of an interface from multiple detected light beams of a different wavelength.

The Cadell et al. disclosure of measuring gel level and height of fluid is different from Applicants' invention. Cadell et al. discloses using *either* an LED array, *or* a diode laser to measure gel level and fluid height. A separate spectrophotometric determination in Cadell et al. measures sample type, temperature, and interferents. Neither the LED array, the diode laser, nor the spectrophotometric determination constitutes a disclosure of first and second light beams of different wavelengths used to determine a sample interface. This claimed feature of Applicants' invention is in fact not taught or suggested by Cadell et al. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of independent Claims 1, 12, 18, 22, and 27, and their dependent claims on this basis.

2. Kawano Does Not Describe Determining The Location Of An Interface.

Kawano describes an analytical method and apparatus for carrying out an analysis of the components of a blood sample, which is a whole blood sample and not separated into interfaces. (*See, e.g.*, Kawano page 1, par. 2-8.) Kawano teaches that blood that has been separated into blood plasma and red blood cells (*i.e.*, separated into layers with an interface) is a problem and that it is the object of the invention to carry out an analysis of the object charactistics of blood (*i.e.*, "the chemical components and physicochemical characteristics . . . of blood such as red blood cells, hematocrit, hemoglobin, total protein, total cholesterol and blood sugar"). (*See, e.g.*, Kawano, page 1, par. 2-9; and page 3, describing the procedure for analyzing the object characteristics of the blood sample.

Nowhere in Kawano is determining interfaces disclosed. Applicants strongly disagree with the assertion of the Office on page 6, lines 7-8 of the Office Action that this feature is disclosed by Figure 1, computer 2, and paragraph 36, lines 1-5 of Kawano. Accordingly, Applicants request withdrawal of the rejection under 35 U.S.C. § 102(e) of Claims 1, 9, and 27 over Kawano.

V. The 35 U.S.C. § 103(a) Rejection.

A. The Invention Is Non-obvious Over Cadell et al.

Claims 2-3, 14-16, and 19-21 are rejected under 35 U.S.C. § 103(a) as unpatentable over Cadell et al. for the reasons stated in numbered paragraph 5 of the Office Action. . It is Applicants position that a *prima facie* case of obviousness for independent Claims 1, 12, 18, 22-23 and 27 and their dependent claims has not been established. Applicants respectfully request consideration of the following remarks, withdrawal of the § 103(a) rejection and allowance of all claims.

As described in Section IV., *infra*, Cadell et al. does not describe all of the claimed limitations of independent Claims 1, 12, 18, 22-23 and 27. Further, Cadell et al. does not provide a suggestion or motivation to modify the reference to project multiple light beams that are transmitted or substantially blocked by different layers in a container to determine a sample interface as claimed by Applicants. Applicants have not merely selected a preferred or optimum container material, or optimum wavelength of light. Applicants discovered that by using light at certain wavelengths, and the spectral properties of certain sample container materials, serum, plasma, gel, and cells that the interfaces in a sample can be determined. Pages 3-4 of the specification describe these spectral properties in further detail.

There is no disclosure in Cadell et al. of the spectral property of serum at long wavelengths of light, i.e., that serum is opaque (substantially blocked) to light at long wavelengths. To the contrary, Cadell et al. teaches using absorbance or transmittance of light to measure gel level and sample height. Thus, there is no suggestion or motivation in Cadell et al. to modify the reference to arrive at Applicants' invention. Accordingly, Applicants submit that all claims are patentable over Cadell et al. and respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a)

B. The Invention Is Non-obvious Over Kawano.

The Office has not rejected the Claims under 35 U.S.C. § 103(a) over Kawano. However, for the sake of completeness, it is Applicants position that Kawano does not support a *prima facie* case of obviousness for independent Claims 1, 12, 18, 22-23, 27 and their dependent Claims.

As described in Section IV, *infra*, Kawano does not describe all of the claimed limitations of independent Claims 1, 12, 18, 22-23 and 27.

Claim 1 is limited to "determining the location of al least one interface from the detected portions". The remainder of the independent claims, Claims 12, 18, 22-23, and 27 are each similarly limited. Kawano does not teach or suggest determining the location of an interface, and in fact, Kawano teaches away from Applicants claimed invention by describing the method for separating the blood into blood plasma and red blood cells (*i.e.*, layers having an interface) as "problematic" and provides a method and apparatus to analyze blood without separating the various components.

Further, Kawano describes the use of 1 light source only and does not provide a suggestion or motivation to modify the reference to project multiple light beams of different wavelengths that are transmitted or substantially blocked by differing layers in a container as claimed by Applicants.

CONCLUSION

Applicants respectfully request entry of the Claim amendments and, based on the forgoing comments, withdrawal of the rejections under 35 U.S.C. §§ 102(e) and 103(a) and allowance of all Claims.

Applicants believe that all pending claims are in condition for allowance and such action is earnestly requested. If the present amendments and remarks do not place the Application in condition for allowance, the Examiner is encouraged to contact the undersigned directly if there are any issues that can be resolved by telephone with the Applicants' representative.

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No fees are believed due by this Response. If, however, any fees are due, the Commissioner is authorized to charge any fees or credit any to Deposit Account No. 19-2090.

Respectfully Submitted,
SHELDON & MAK PC

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